



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|------------------------|------------------|
| 10/634,567 | 08/05/2003 | A. Wesley Prais | 102-523 DIV/CON/CIP II | 6974 |

32752 7590 12/15/2006

DAVID W. HIGHET VP & CHIEF IP COUNSEL
SECTION DICKINSON AND COMPANY
1 BECTON DRIVE MC 110
FRANKLIN LAKES, NJ 07417-1880

EXAMINER

KOHARSKI, CHRISTOPHER

ART UNIT PAPER NUMBER

3763

DATE MAILED: 12/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|-------------------------------------|------------------------------|--|
| Office Action Summary | Application No. 10/634,567 | Applicant(s) PRAIS ET AL. | |
| | Examiner Christopher D. Koharski | Art Unit 3763 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 November 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-59 is/are pending in the application.
- 4a) Of the above claim(s) 11-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 and 19-59 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>10/31/03</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Claims 11-18 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected group (group I selected), there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 11/13/2006.

Currently claims, 1-10 and 19-59 are pending for examination in this application.

Information Disclosure Statement

The information disclosure statement (IDS) that was submitted on 10/31/2003 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the examiner is considering the information disclosure statement.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Art Unit: 3763

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 9-10, 19, 26-28, 36-38, 48-50 and 58-59 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 5,752,942 and claims 1, 3, 11, 12 and 18 of U.S. Patent No. 6,629,963. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in the current pending application are anticipated by the claims in the cited US patent.

Application claim 1 requires:

1. A syringe assembly comprising:
 - a syringe barrel; and,
 - a needle cannula supported by said syringe barrel, said needle cannula having a central axis, an outer diameter in the range of .0130" - .0135", and an inner diameter in the range of .0075" - .0090", said needle cannula having a multi-beveled point including a plurality of planar bevels extending at different angles relative to said central axis, including a primary bevel, a pair of tip bevels and a pair of middle bevels intermediate said primary bevel and said tip bevels.

While patent claim 1 (5,752,942) requires:

1. A needle having a multi-beveled point, comprising:
 - a cannula having a lumen and a central axis therethrough, said multi-beveled point provided at one end of the cannula, said multi-beveled point comprised of a primary bevel, a pair of tip bevels, and a pair of middle bevels, each of said pair of middle bevels

Art Unit: 3763

intermediate said primary bevel and one of said pair of tip bevels, wherein each of said pair of tip bevels meets a respective middle bevel at an intersection line, wherein respective of angles defined between said central axis and a reference plane, said primary bevel is provided on said cannula at a first planar angle, said pair of middle bevels are provided on said cannula at a second planar angle, and said pair of tip bevels are provided on said cannula at a third planar angle, and wherein respective of an angle of rotation about said central axis, said primary bevel is provided at a first rotational angle, said pair of middle bevels are each provided at a second rotational angle, and said pair of tip bevels are each provided at a third rotational angle, wherein said first and second planar angles are substantially equal.

While patent claim 11 (6,629,963) requires:

11. A syringe assembly, comprising: a generally tubular syringe barrel; a needle cannula supported by and extending from said syringe barrel including a lumen extending therethrough defining a central axis and a five-beveled point comprising a plurality of planar bevels extending at different angles of rotation relative to said central axis, including a primary bevel, a pair of tip bevels and a pair of middle bevels intermediate said primary bevel and said tip bevels; and a needle shield having an open end and a passage through said open end configured to receive said needle cannula and said needle cannula disposed therein, wherein said needle shield is formed of a styrene block thermoplastic elastomer having a Shore A hardness of between 30 and 90 and a gas permeability sufficiently high to permit gas sterilization through said needle shield.

Thus it is apparent that the application claims are narrower than the patent claims and the subsequent patented independent and dependant claims (drawn to the materials and characteristics of the needle shield) of the patents above encompass application claims 1, 9-10, 19, 26-28, 36-38, 48-50 and 58-59. Following the rationale in *In Re Goodman* cited in the preceding paragraph, where Applicant has once been granted a patent containing a claim for the specific or narrower invention, Applicant may not then obtain a second patent with a claim for the generic or broader invention without first submitting a terminal disclaimer.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-8, 19-25, 28-35 and 38-47 are rejected under 35 U.S.C 103(a) as being unpatentable over Baldwin et al. (3,071,135).

Regarding claims 1-8, 19-25, 28-35 and 38-47, Baldwin et al. discloses a needle cannula comprising a needle (10) with a plurality of bevels with different angles relative to the central axis, with a primary bevel (17), a pair of tip bevels (13), and a pair of middle bevels (12) located intermediate to said tip bevel and primary bevel. Additionally the bevels angles with respect to the angles between the bevel angles each bevel has a distinct plane located a specific rotational angle (Figures 1-5).

Baldwin et al. meets the claim limitations as described above except for a needle inner and outer diameter, cannula thickness, and bevel planar angle ranges as claimed by Applicant and syringe barrel.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the reference using Applicant's needle ranges, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980). Additionally, if not inherent it would be obvious to use the cannula hypodermic needle with a syringe barrel such as Hausser (5,385,555).

Claim Rejections - 35 USC § 103

Claims 50-57 are rejected under 35 U.S.C 103(a) as being unpatentable over De Luca.

Regarding claims 1-8, 19-25, 28-35 and 38-47, De Luca discloses a needle cannula comprising a needle (10) with a plurality of bevels with different angles relative to the central axis, with a primary bevel (12), a pair of tip bevels (21,22), and a pair of middle bevels (23,24) located intermediate to said tip bevel and primary bevel.

Art Unit: 3763

Additionally the bevels angles with respect to the angles between the bevel angles each bevel has a distinct plane located a specific rotational angle (Figures 1-13).

De Luca meets the claim limitations as described above except for a needle inner and outer diameter, cannula thickness, and bevel planar angle ranges as claimed by Applicant and syringe barrel.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the reference using Applicant's needle ranges, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980). Additionally, if not inherent it would be obvious to use the cannula hypodermic needle with a syringe barrel such as Hausser (5,385,555).

Claim Rejections - 35 USC § 103

Claims 9-10, 26-27, 36-37, 48-49 and 58-59 are rejected under 35 U.S.C 103(a) as being unpatentable over Baldwin et al. (or De Luca) in view of Hausser (5,385,555). Baldwin et al. (or De Luca) meets the claim limitations as described above except for a needle shield with the specific Shore hardness's as claimed.

However, Hausser teaches a lockable safety shield for a hypodermic syringe.

Regarding claims 9-10, 26-27, 36-37, 48-49 and 58-59, Hausser teaches a needle shield (36) composed of a thermoplastic material (Figures 1-3).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the needle shield of Hausser with the needle shield material properties as claimed by Applicant, since it has been held to be within the

Art Unit: 3763

general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960).

At the time of the invention, it would have been obvious to use the needle shield of Hausser with the needle of Baldwin et al. (or De Luca) because the needle shield aids in user safety and protection against needle sticks. The references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Hausser.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher D. Koharski whose telephone number is 571-272-7230. The examiner can normally be reached on 7:30am to 4:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3763

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Date: 12/8/2006

COK
Christopher D. Koharski
AU 3763

akel
[Faint, illegible text]